DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

December 27, 2004

WARNING LETTER NO. 2005-NOL-08

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. R. Steven Boggan, President and CEO
BioHorizons Implant Systems, Inc.
One Perimeter Park South
Suite 230, South
Birmingham, Alabama 35243

Dear Mr. Boggan:

During October 26-29 and November 1-2, 2004, a United States Food and Drug Administration (FDA) investigator inspected your firm, located at One Perimeter Park South, Suite 230, South, Birmingham, Alabama. FDA has determined your firm manufacturers various Class I, II, and III dental devices, including endosseous implants. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). You may find the Act and associated regulations through links at FDA's home page at www.fda.gov.

The inspection revealed your devices are adulterated within the meaning of Section 501(h) of the Act, as methods used in, or facilities or controls used for design, manufacturing, packing, labeling, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation for medical devices, as specified in Title 21, *Code of Federal Regulations*, Part 820 (21 CFR 820).

At the close of the inspection, you were issued a list of Inspectional Observations, Form FDA 483, which identified a number of significant QS regulation violations including, but not limited to, the following:

1. You failed to ensure an adequate and effective Quality System has been implemented and maintained at all levels of your organization, as required by 21 CFR 820.20 (FDA 483, Item 1). For example, under these regulations, you are responsible for conducting sufficient and regular internal quality system audits, evaluations of suppliers/contractors, and sufficient management review meetings. You have not conducted internal audits of your quality system in the past [redacted] years, as required by 21 CFR 820.22, and management review meetings are not convened at defined intervals and with sufficient frequency, as required by 21 CFR 820.20(c).

2. You failed to document each batch of finished devices meets acceptance criteria before release for distribution, as required by 21 CFR 820.80(d) (FDA 483, Item 2). Specifically, device history records (DHR) for the 160-500 Maestro Surgical Kit, the 160-300 Maximus Surgical Kit, and th[redacted], do not document confirmation that each kit contains all required components and each component is placed in its proper compartment within each kit. Further, the available records are transcribed from original working documents, which are not maintained. Original records documenting activities as they occur should be maintained in DHRs.

3. You failed to conduct follow-up investigations to complaints involving the possible failure of your devices to meet specifications and failed to document the reason why no investigation was conducted, as required by 21 CFR 820.198(b) and (c) (FDA 483, Items 4 & 5). Specifically, our investigator collected [redacted] complaints involving the Maestro Implant dated between July and September 2004. These records establish that no one conducted an investigation in response to these complaints, nor did anyone record any reason explaining why no investigation was conducted.

4. You failed to conduct and/or document adequate corrective and preventive action in response to complaints involving the possible failure of your device to meet its specifications, as required by 21 CFR 820.100(a) and (b) (FDA 483, Items 6 & 7). Regarding the [redacted] complaints mentioned in item three above, there is no record of any corrective and preventive action taken in response to the complaints. Further, your 2004 [redacted] complaint summaries for management review fail to document your firm conducted any comparative analysis of your complaint data. For example, your 2004 summaries report [redacted] complaints involving failure to osseointegrate, which includes infection as a cause. These summaries fail to include specific data on the devices, such as lot number, model, or specifications, or any other vital trending data. Because of this, you may fail to detect and prevent recurring quality problems, which may be causing the device failures identified in the complaints.

We are aware you made a verbal commitment at the close of your inspection on November 2, 2004, to correct observed deficiencies. Also, we are in receipt of [redacted] Vice-President, Quality Assurance and Regulatory Affairs, response, dated November 11, 2004, to our November 2, 2004, Form FDA 483. FDA will file your November 11, 2004, response in your firm's official file and will review it in conjunction with your response to this letter.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It remains your responsibility to ensure adherence to all requirements of the Act and regulations. The specific violations noted in this letter and Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until violations related to subject devices have been corrected.

You should take prompt action to correct these violations. Failure to correct these violations promptly may result in regulatory action by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken, or will take, to identify and correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to ensure similar violations will not recur.

Please send your reply to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,

F. Dwight Herd

F. Dwight Herd
Acting District Director
New Orleans District

Enclosure: Form FDA 483
21 CFR 820

cc: [redacted] Vice-President
Quality Assurance and Regulatory Affairs
BioHorizons Implant Systems, Inc.
One Perimeter Park South
Suite 230, South
Birmingham, Alabama 35243